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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

09/735,408

12/11/2000

Ronald K. Yamamoto

ISC9901U

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LEARY & ASSOCIATES  
3900 NEWPARK MALL RD.  
THIRD FLOOR, SUITE 317  
NEWARK, CA 94560

EXAMINER

BOUCHELLE, LAURA A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

10/16/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

09/735,408

**Applicant(s)**

YAMAMOTO ET AL.

**Examiner**

Laura A. Bouchelle

**Art Unit**

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-49 and 66-75 is/are pending in the application.
- 4a) Of the above claim(s) 5, 9, 11-17, 30, 35, 36, 40, 41, 44 and 47-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8, 10, 18-29, 31-34, 37-39, 42, 43, 45, 46 and 66-75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/26/07 has been entered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 20, 24, 67-71, 73-75 are rejected under 35 U.S.C. 102(b) as being anticipated by Barken (US 5531742). Barken discloses an apparatus for computer controlled surgery comprising a locating means such as an ultrasound imaging system capable of non-invasively locating Schlemm's canal in an eye, a microsurgical device coupled with the locating means and using location data to advance a microsurgical device into tissue space. The location data consists of real-time data collected by the location means (Col. 2, lines 1-5, 15-23, Col. 3, lines 30-36, 53-54).

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***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barken in view of Thomas III et al (US 4911170). Claims 6 and 7 differ from Barken in calling for the examination of the sclera with an ultrasound frequency greater than 10 MHz or at least 40 MHz. Thomas discloses, as does applicant in the background of the invention, an image ultrasound catheter system that uses frequency of 20-50MHz to image the fine structures of tissues. Therefore, it would have been obvious to one of ordinary skill at the time of invention to modify the device of Barken to use ultrasound at a frequency of 25-50 MHz as taught by Thomas so that the finer structure of the tissues could be visualized.

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marker in view of Bernstein (US 6132699). Claim 8 differs from Barken in calling for the locating means to utilize an ultrasound contrasting tracer. Bernstein teaches the use of an ultrasound contrast introduced into the body of interest to enhance detection and observation of certain physiological and pathological conditions (Col. 1, lines 29-33). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Barken to include the use

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of an ultrasound contrast agent as taught by Bernstein to enhance detection and observation of certain physiological and pathological conditions.

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barken in view of LeBlanc et al (US 5989189). Claim 10 differs from Barken in calling for the locating means to comprise a transducer assembly with signaling means for directing the transducer location. LeBlanc teaches the use of an ultrasound transducer with a signaling means in order to detect, not only typical eye structures such as the cornea, retina, sclera, etc, but also aberrations such as tumors and blood trapped within an eye's vitreous (Col. 1, lines 16-27). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Barken to incorporate a transducer assembly with a signaling means as taught by LeBlanc in order to detect the above mentioned structures in the eye.

13. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barken in view of Schachar (US 6146366). Claim 18 differs from Barken in calling for the surface of the locating means to be curved to approximate the surface of the eye. Schachar teaches the use of a device used for the treatment of eye disorders, which has a surface that contacts the eye that is curved in order to provide an approximate match for the curvature of the surface of the eye (Col. 9, lines 53-56). See Fig. 6. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Barken so that the tissue contacting surface is curved as taught by Schachar to provide an approximate match for the curvature of the surface of the eye.

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15. Claims 19, 27-29, 31, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barken in view of Steen et al (US 5984904). Claim 19 differs from Shahidi in calling for the tissue-contacting portion to incorporate a circumferential raised portion to maintain placement of a coupling fluid over a transducer face. Steen teaches the use of a surgical instrument to perform eye surgery which contains several raised portions in the form of an array of protuberances projecting from an interior wall surface and spaced apart in longitudinal and transverse directions so as to define a network of generally uniform channels extending between adjacent protuberances 40 for fluid flow about each protuberance in a longitudinal and transverse direction (Col. 4, lines 7-12). See Figs. 4-7. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Barken to have protuberances as taught by Sheen to form a channel to maintain placement of a fluid around the entire circumference of an instrument.

17. Claims 27 and 29 differ from Barken in calling for the microcannula or the inner cannula to incorporate a cutting tip to penetrate the sclera of the eye. Steen teaches the use of a microcannula or inner cannula 26 with a cutting tip 16 capable of cutting the sclera of the eye during a surgical procedure of the eye (Col. 4, line 8). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Barken to include a cutting tip as taught by Sheen to remove the sclera during a procedure on the eye.

18. Claims 28 and 31 differ from Barken in calling for the microcannula to comprise a flexible outer sheath and an inner cannula. Sheen teaches the use of a pliable outer sheath 10 and an inner cannula 26 to facilitate insertion into the eye during surgery (Col. 2, lines 55-58). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention

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to modify the device of Barken to include a flexible outer sheath and an inner cannula as taught by Sheen to facilitate insertion of the device into the eye during surgery.

19. Claim 46 differs from Barken in calling for the device to have a surgical tool for cutting tissues. Steen teaches the use of a construct 16 delivered through a microcannula 26, which comprises a surgical tool for cutting tissues in order to remove the natural lens from an eye during a surgical procedure. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Barken to include a surgical tool for cutting tissues as taught by Sheen to enable the device to remove tissue from the eye during a surgical procedure.

20. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barken. Barken discloses a microcannula 109 (Col. 4, line 8) but does not specify a size of less than 200 microns. It would have been obvious to one of ordinary skill in the art to modify the microcannula of Barken to limit the size to be less than a specific measurement, such as 200 microns, in order to accommodate the use of the cannula in a correspondingly small space.

21. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barken in view of Imling et al (US 6203499). Claims 22 and 23 differ from Barken in calling for the microcannula to be coupled to the locating means at an adjustable angle such as an angle between 0 and 30 degrees. Imling teaches the use of a multiple angle needle guide that can be

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coupled to an imaging system (Col. 1, lines 36-44) in order to allow the needle to be adjusted to any angle, such as one between 0 and 30 degrees. See Fig. 1. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Barken to include a multiple angle guide as taught by Imling so that the needle can be coupled to the locating means at an angle between 0 and 30 degrees to ensure that the needle can be effectively maneuvered in the direction indicated by the locating means.

23. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barken in view of Simon (US 4883053). Claim 25 differs from Barken in calling for the microcannula to be coupled to the locating means using a clip mechanism. Simon teaches the use of a chop mechanism 68a, 68b to couple a cannula 66 to another device 50 in order to assure that the coupling is secure. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Barken to include a clip mechanism a taught by Simon to securely couple the cannula to the locating means.

25. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barken in view of Mohr, Jr et al (US 5921954). Claim 26 differs from Shahidi in calling for a distal portion of the cannula to be curved to accommodate a curvature of Schlemm's Canal. Mohr discloses a cannula to be used in treating a myriad of body structures, where the cannula tip 101 may comprise a curved needle-like shape adapted to a surface of curvature of an eye, so the cannula tip 101 can be used easily with on a procedure on the eye (Col. 3, lines 39-42). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify



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the cannula of Barken by curving the tip of the cannula as taught by Mohr so that it may be used easily with the eye.

27. Claims 32-34, 37, 38, 45, 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barken in view of Lynch et al (US 6524275). Claims 32-34 differ from Barken in calling for a dilation mechanism on the tip of the cannula. Lynch discloses an inflatable device and method for treating glaucoma that teaches the use of a dilation mechanism on the tip of a cannula 50, which consists of an inflatable sleeve such as a balloon which is placed within Schlemm's canal and the inflatable element of the device is expanded to temporarily stretch and expand the lumen of the canal. At that point, the inflatable element may be used to temporarily occlude outflow through the canal, while physiologic material is injected through another lumen of the device, thereby distending the canal and expanding areas of stenosis within the canal (Col. 3, lines 56-65). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cannula of Barken to incorporate a dilation mechanism, such as the inflatable balloon on the tip of the cannula as taught by Lynch for placement within Schlemm's Canal in order to temporarily stretch and expand the lumen of the canal.

29. Claim 38 differs from Barken in calling for an implant being delivered into Schlemm's Canal. Lynch teaches an implant being delivered into Schlemm's Canal (Col. 5, lines 4-12) in order to maintain patency within the canal to facilitate the natural drainage of the aqueous humor. Therefore, it would have been obvious to one of ordinary skill in the art to modify the

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invention of Barken to include an implant that is delivered into Schlemm's Canal as taught by Lynch in order to maintain patency within the canal the facilitate the natural drainage of the aqueous humor.

30. Claim 45 differs from Barken in calling for a construct to be delivered through a microcannula. Lynch teaches a construct being delivered through a microcannula 100 (Col. 5, lines 4-12) to effect a surgical procedure on a trabecular meshwork of the eye (Col. 7, lines 15-19). Therefore, it would have been obvious to one of ordinary skill in the art to modify the invention of Barken to include a construct delivered through a microcannula as taught by Lynch in order to effect a surgical procedure on a trabecular meshwork of the eye.

31. Claims 39 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barken in view of Lafont et al (5,957,975). Claims 39 and 42 differ from Barken in calling for the use of an expandable or biodegradable stent. Lafont teaches the use of an expandable biodegradable stent for the purpose of enlarging a lumen or canal within the body that will degrade within the body and eliminates the need for removal of the stent. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Barken and add an expandable stent as taught by Lafont for the purpose of enlarging a lumen or canal within the body, such as Schlemm's Canal that will degrade with the body and eliminate the need for removal of the stent.

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***Response to Arguments***

8. Applicant's arguments with respect to claims 1-4, 20, 24, 67-71, 73-77 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



**NICHOLAS D. LUCCHESI**  
**SUPERVISOR & EXAMINER**  
**TECHNOLOGY CENTER 3700**

Laura A Bouchelle  
Examiner  
Art Unit 3763

